

### Remarks

Claims 12, 16-28 and 31-43 are pending in the subject application. By this Amendment, Applicants have amended claims 12 and 31. Support for the amendments can be found throughout the subject specification and in the claims as originally filed (see, for example, pages 5-6 of the as-filed specification). Entry and consideration of the amendments presented herein is respectfully requested. Accordingly, claims 12, 16-28 and 31-43 are currently before the Examiner. Favorable consideration of the pending claims is respectfully requested.

Applicants gratefully acknowledge the Examiner's withdrawal of the objections to claims 12, 30, 31 and 40 and the rejections under 35 U.S.C. § 112, first and second paragraphs.

Claims 12, 16-28 and 31-43 remain rejected under 35 U.S.C. § 112, first paragraph, as nonenabled by the subject specification. Applicants respectfully assert that the claims as filed are enabled. The Office Action indicates that this argument has been fully considered but is not found persuasive. In an effort to advance prosecution in this matter, the claims have been amended in a manner that adopts the suggestion of the Examiner at page 4 of the Office Action dated May 27, 2010. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, first paragraph, is respectfully requested.

Claims 12, 16, 17, 19-27, 31-33, 35-39 and 41-43 remain rejected under 35 U.S.C. § 102(b) as anticipated by Acosta *et al.* (1991) as evidenced by Moeman *et al.* (2008). Applicants again respectfully assert that the Acosta *et al.* reference does not anticipate the claimed invention.

As noted previously, it is well settled that in order for the Patent Office to establish a *prima facie* case of anticipation, each and every element of the claimed invention, arranged as required by the claim, must be found in a single prior art reference, either expressly or under the principles of inherency. *See generally In re Schreiber*, 128 F.3d 1473, 1477; *Diversitech Corp. v. Century Steps, Inc.*, 850 F.2d 675, 677-78 (Fed. Cir. 1988); *Lindemann Maschinenfabrik GmbH v. American Hoist and Derrick*, 730 F.2d 1452, 1458 (Fed. Cir. 1984). In this case, the claims require diagnosing a male as having XX disomy or YY disomy and administration of FSH for reducing or treating the rate of gamete numerical chromosomal alteration in a male. The Acosta *et al.* reference does not teach diagnosing a male with a gamete numerical chromosomal alteration that is XX or YY disomy and treating such a diagnosed individual. Acosta *et al.* teaches that two groups of male patients were

treated with FSH: a) patients with a history of failed fertilization in previous *in vitro* fertilization (IVF) attempts and b) patients with poor sperm parameters (Acosta *et al.* at page 1151, column 1, paragraph 3, lines 6-11). Sperm parameter criteria were: (1) a poor prognosis morphology pattern and severe impairment of other parameters (sperm concentration and/or motility); and (2) a consistent recovered motile fraction of  $< 1.5 \times 10^6$ , regardless of other parameters (Acosta *et al.* at page 1151, column 2, paragraph 2, lines 9-16). Clearly absent from the teachings of the reference is the diagnosis of a male with a gamete numerical chromosomal alteration that is XX or YY disomy.

In responding to the previously presented arguments, the Office Action argues that the Acosta *et al.* reference “clearly discusses diagnosis using the same criteria as are outlined in the specification at pages 6 and 7 (see p. 1151 of Acosta *et al.*, under Materials and Methods). Acosta *et al.* disclose patients having the same level of extreme male infertility characterized by low sperm concentration, impaired motility and abnormal morphology that was taught in Moeman *et al.* (see p. 1151, 3rd paragraph of Acosta *et al.*). The Moeman reference provides evidence that there is a significant correlation between OAT and XX and XY disomy, thus they teach that semen quality do equate with XX and XY gamete chromosomal alteration in individuals” (Office Action at page 7). Applicants submit that these arguments fail to support a finding that the claims are anticipated.

The sections referred to in the Office Action relate to definitions of various terms used in the application (for example, “Oligozoospermia”, “Teratozoospermia”, “Oligoastheno-teratozoospermia”, *etc.*) and are unrelated to how one diagnoses aneuploidy, diploidy or disomy. Aneuploidy, diploidy, or disomy is determined by fluorescence *in situ* hybridization (FISH; see page 10, paragraph 1 and page 15, paragraph 1 of the as-filed specification). Other techniques used to diagnose aneuploidy, diploidy, or disomy include karyotyping, FISH or PCR techniques (Hulten *et al.*, Reproduction, 2003, 126:279-297, a copy of which is attached for the Examiner’s convenience). Acosta *et al.* fail to teach diagnosis of aneuploidy, diploidy or disomy using such techniques and the techniques used in the reference would not allow the diagnosis of aneuploidy, diploidy or disomy.

Furthermore, Moeman *et al.* indicate that “although analysis of semen parameters could provide some indication of the function of the testis and spermatozoa, it does not provide information on the condition of the male genome contained in sperm heads” (see page 381, column 2, first full paragraph). Thus, the use of sperm parameters, such as those disclosed in Acosta *et al.*

cannot, as argued in the Office Action, meet the step of diagnosing XX or YY disomy. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

Claims 18 and 34 remain rejected under 35 U.S.C. § 103(a) as obvious over Acosta *et al.* (1991) and as applied to claims 12, 16, 17, 19-27, 31-33, 35-39 and 41-43 above and further in view of Loumaye *et al.* (1995). Applicants respectfully assert that the claimed invention is not obvious over the cited references.

As discussed previously, an obviousness rejection fails if the prior art relied on does not disclose all of the limitations of the claimed invention. *See, e.g., In re Zurko*, 258 F.3d 1379, 1385-86 (Fed. Cir. 2001). Thus, obviousness requires a teaching or suggestion of all limitations in a claim. *CFMT, Inc. v. Yieldup Intern. Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003) (citing *In re Royka*, 490 F.2d 981, 985 (C.C.P.A. 1974)). As noted above, Acosta *et al.* fail to teach a step of diagnosing XX or YY disomy. Loumaye *et al.* fail to remedy this defect in the teachings of Acosta *et al.* Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. § 103(a) is respectfully requested because each of the limitations of the claimed invention is not taught by the cited combination of references.

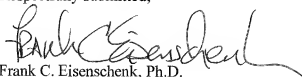
It should be understood that the amendments presented herein have been made solely to expedite prosecution of the subject application to completion and should not be construed as an indication of Applicants' agreement with or acquiescence in the Examiner's position. Applicants expressly reserve the right to pursue the invention(s) disclosed in the subject application, including any subject matter canceled or not pursued during prosecution of the subject application, in a related application.

In view of the foregoing remarks and amendments to the claims, Applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

Applicants invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



Frank C. Eisenschenk, Ph.D.

Patent Attorney

Registration No. 45,332

Phone No.: 352-375-8100

Fax No.: 352-372-5800

Address: P.O. Box 142950

Gainesville, FL 32614-2950

FCE/jb

Attachment: Hulten *et al.*, 2003